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REMARKS

This paper is responsive to the Office Action mailed December 15, 2006. All claims 1-5, 7-24 and 29-32 were rejected in the Office Action. Claims 5 and 15 have been canceled in this paper.

Section 102(b) rejections.

Claims 1, 2, 5, 7, 8, 13-16 and 30 were rejected under 35 U.S.C. §102(b) as being anticipated by Raulerson (USP 5,045,065). The Examiner has specifically identified the embodiment of Fig. 9 of Raulerson as forming the basis of this rejection.

The present invention is directed to a percutaneous entry system, and more particularly, to an insertion system for substantially bloodless percutaneous entry into a body vessel. As stated in the Background section of the present application, when medical percutaneous entry systems were originally developed, a clinician would typically insert a needle through the skin and into a body vessel, such as an artery. Visual proof that the needle tip was in the correct location was obtained when a "squirt" of blood shot out of the needle hub. As concern arose in subsequent years about the dangers of blood borne pathogens, health regulations were implemented to restrict exposure of the medical workers to blood. As a result, many devices have been developed to seek substantially bloodless entry, and thereby limit the exposure of medical personnel to blood and other body fluids. The present device represents an advancement of this technology.

Claim 1 of the application, as amended herein, is directed to a percutaneous insertion system comprising a needle assembly, a needle hub attachment assembly, and an assembly comprising a hemostatic segment. Each of the respective assemblies has a passageway extending therethrough, wherein the passageways are aligned in the assembled device in a manner such that a path is formed therebetween, e.g., for insertion of a wire guide therethrough. The needle hub attachment assembly

of the claimed system comprises a chamber communicating with the needle assembly for receiving body fluid through the needle. The distal end of the assembly comprising a hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. This latter limitation was originally present in claim 5, which claim has now been canceled.

The Examiner has identified structure in Raulerson that is said to meet the limitations of the claimed insertion system. However, Applicants respectfully submit that the claimed system is actually quite different from the Raulerson system. For example, as stated above, the needle hub attachment assembly of the claimed insertion system has a chamber 26 communicating with the needle assembly for receiving the body fluid withdrawn through the needle. When blood collects in the chamber, the clinician can visually confirm the presence of blood in the chamber. This provides positive proof that the needle has entered the artery or the vein. No such structure is apparent in the "needle hub attachment assembly" of the Raulerson system.

In addition to the foregoing, the distal end of the assembly comprising a hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. This may be observed in Fig. 2, wherein assembly 40 includes tapered distal portion 42 that tapers to endhole 43 having a diameter substantially the same as the diameter of the wire guide. The presence of the taper is significant in view of the overall purpose of the system, that is, to provide a substantially bloodless system for withdrawing a body fluid. When the assembly 40 is tapered to the diameter as described, the possibility of leakage of blood through the system is diminished, due to the close tolerance between the tapered end of the assembly and the outer diameter of the wire guide. In the system of Raulerson, the Examiner has identified cylindrical body 30 as meeting the limitation of the assembly having a hemostatic segment. However, it is clear that cylindrical body 30 of Raulerson does not taper, and more particularly, does not taper to a diameter

substantially the same as the diameter of the wire guide. As a result, the beneficial aspects of the taper would not be realized with the Raulerson design.

Thus, for at least the foregoing reasons, Applicants respectfully submit that claim 1, as well as dependent claims 2, 7, 8, 13, 14 and 16 are not anticipated by Raulerson.

Applicants further call the Examiner's attention to a particularly preferred embodiment as claimed in dependent claim 8. According to claim 8, the valve (e.g., ref. no. 44 in Fig. 2) tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. This tapered configuration allows blood to collect circumferentially along the exterior of the tapered portion. As a result, circumferential pressure exerted around the valve within the system will cause the taper to collapse and form a seal. This is further described, e.g., at paragraph [0031] of the application. The Examiner has identified valve 28 of Raulerson as meeting the limitations of the valve in the claimed system. However, it is clear that the valve of Raulerson does not taper to an endhole having a diameter substantially the same as the diameter of the wire guide. As a result, the beneficial aspects of the inventive system would not be realized by the device disclosed in Raulerson for this additional reason.

Independent claim 30 is directed to a percutaneous insertion system comprising a needle assembly, and an assembly having a hemostatic segment. The assembly comprising the hemostatic segment includes a valve at the proximal end of said assembly that tapers in a distal direction to an endhole having a diameter substantially the same as the diameter of the wire guide. As stated above, the device disclosed in Raulerson does not include a valve having this tapered configuration. Thus, for at least the foregoing reason, claim 30 is also not anticipated by Raulerson.

Sec. 103(a) rejections.

Claims 3, 4, 12 and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Raulerson in view of Raulerson II (USP 6,551,281). Raulerson II was cited for teaching a guidewire advancer comprising a guidewire holder that is preloaded with a guidewire, and wherein the holder may maintain the guidewire in a loop. However, claims 3, 4 and 12 depend from claim 1, and therefore include all of its limitations, including the limitations of a chamber and a tapered hemostatic segment as described. Claim 32 depends from claim 30, and includes all of its limitations, including the limitation of a hemostatic segment including a valve at the proximal end of said assembly that tapers in a distal direction to an endhole having a diameter substantially the same as the diameter of the wire guide. Raulerson II does not teach or suggest such features. Accordingly, claims 3, 4, 12 and 32 are not obvious in view of the cited combination.

Claims 9, 10, 17, 18, 21-24 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Raulerson in view of Vaillancourt (USP 6,699,221). Vaillancourt was cited for teaching an elastomeric valve that allows for insertion of a wire guide therethrough. Claims 9 and 10 depend from claim 1 and include all of its limitations, including the limitations of a chamber and a tapered hemostatic segment as described. Vaillancourt does not teach or suggest such features. Accordingly, claims 9 and 10 are not obvious in view of the cited combination.

Independent claim 17, as amended, is directed to a percutaneous insertion system comprising, among other things, a needle assembly having a first hemostatic segment, and an assembly having a second hemostatic segment configured for leak-free engagement with the needle assembly. The second hemostatic segment comprises a valve positioned at the proximal end of the assembly, and has an opening permitting passage of a wire guide therethrough. The distal end of the assembly comprising the second hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. Neither Raulerson

nor Vaillancourt teaches or suggests a percutaneous entry system having first and second hemostatic segments as described. Although each reference includes structure that the Examiner has considered as a hemostatic segment, there is no suggestion in either reference to combine hemostatic segments in each portion (or assembly) of the inventive percutaneous insertion system. In addition, neither reference teaches or suggests an arrangement of first and second hemostatic segments, wherein the distal end of the second hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. Accordingly, Applicants respectfully submit that claim 17 is not obvious in view of the cited combination.

Claims 18 and 21-24 depend, directly or indirectly, from independent claim 17, and therefore include all of its limitations, including the limitations recited above. Accordingly, these claims are not obvious for at least the same reasons that claim 17 is not obvious.

Claim 29 depends from claim 1, and therefore includes all of its limitations, including the limitations of a chamber and a tapered hemostatic segment as described. Vaillancourt does not teach or suggest such features. Accordingly, claim 29 is also not obvious in view of the cited combination.

Claims 11 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Raulerson in view of Padilla (USP 5,984,895. Padilla was cited for teaching a transparent needle hub attachment assembly. Claim 11 depends from claim 1, and therefore includes all of its limitations, including the limitations of a chamber and a tapered hemostatic segment as described. Claim 31 depends from claim 30 and includes all of its features, including the limitation of a hemostatic segment including a valve at the proximal end of the assembly that tapers in a distal direction to an endhole having a diameter substantially the same as the diameter of the wire guide. Padilla does not teach or suggest such features. Accordingly, claims 11 and 31 are not obvious in view of the cited combination.

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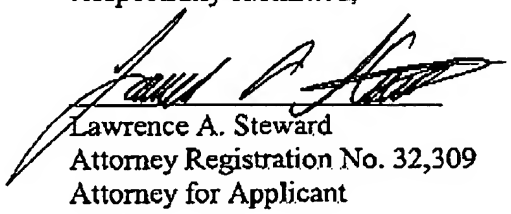
Claim 19 was rejected under 35 U.S.C. §103(a) as being unpatentable over Raulerson in view of Vaillancourt as applied to claim 17, and further in view of Raulerson II. Claim 20 was were rejected under 35 U.S.C. §103(a) as being unpatentable over Raulerson in view of Vaillancourt as applied to claim 17, and further in view of Padilla. Claims 19 and 20 depend from claim 17 and include all of its limitations, including the limitations of a percutaneous entry system having first and second hemostatic segments as described, and wherein the distal end of the second hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. Accordingly, claims 19 and 20 are not obvious in view of the cited combinations.

Conclusion:

Based upon the foregoing, Applicants respectfully submit that the grounds for rejection of the claims have been overcome, and that all claims 1-4, 7-14, 16-24 and 29-32 are in condition for allowance. If the Examiner believes that prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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